

**Premarket Approval (PMA) Package for  
Dockets Management Branch**

**PMA Number P040042  
Docket # 2005M-0476**

**Irvine Biomedical, Inc.  
Therapy™ Dual 8™ Cardiac Ablation System**

**Includes:**

**Approval Order  
Summary of Safety and Effectiveness Data (SSED)  
Labeling**

*2005M-0476*

*AAV1*